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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,799

03/30/2005

Lee Ann Olson

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5362

50855

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10/22/2008

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EXAMINER

LOPEZ, MICHELLE

ART UNIT

PAPER NUMBER

3721

MAIL DATE

DELIVERY MODE

10/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,799	Applicant(s) OLSON ET AL.	
	Examiner Michelle Lopez	Art Unit 3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-36 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed on July 7, 2008.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 3/3/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 32-36 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontayne USPN 5485952 in view of Milliman USPN 5865361 and Bolanos et al. USPN 5897562.** With respect to claims 32 and 35, Fontayne discloses the claimed tool assembly comprising an anvil 18 and a cartridge assembly 16, the cartridge having a plurality of staples 302 and being movable in relation to the anvil between an open and an approximated position as shown in figs. 7 and 10, the cartridge and anvil defining a tissue gap in the approximated position as shown in figs. 12-14; a clamp collar 90 being movable between a first and a second position to effect movement of the anvil in relation to the cartridge from the open position

Art Unit: 3721

towards the approximated position as shown in fig. 10, wherein in the second position the clamp collar 90 is positioned about the proximal ends of the cartridge and anvil assemblies; a dynamic clamping member 280 movably positioned in relation to the anvil and cartridge assembly from a first position as shown in fig. 12 to a second position as shown in fig. 14.

4. Although Fontayne's clamping member 280 slidably engages the cartridge assembly, Fontayne fails to disclose a mechanical interface which slidably engages the anvil assembly. Milliman shows a tool assembly 17 including an anvil 20, a cartridge 18, and a dynamic clamping member with a first and a second mechanical interface as claimed (see Figs. 45, 49, 51-52) for the purpose of press together the anvil and cartridge assembly to uniformly maintain a gap between tissue contacting the anvil and the cartridge during the slidably forward movement of said clamping member within the tool assembly. It would have been obvious to one having ordinary skill in the art to have provided Fontayne's dynamic clamping member 280 having a first and second mechanical interfaces as taught by Milliman to maintain engagement of said clamping member with both the anvil and cartridge during forward movement of said clamping member within the tool assembly providing a uniform tissue gap during the ejection of the staples.

5. With respect to the last paragraph of claim 32, although Fontayne shows a flexible actuator link 155 operatively associated to the clamping member 280 to effect movement of said clamping member between a first and a second position, Fontayne fails to disclose wherein said flexible actuator link is a pulley mechanism operatively associated with the clamping member. Milliman also fails to disclose at least one pulley operatively associated to the dynamic clamping member to effect movement of it. However, Bolanos teaches the concept of a surgical tool

Art Unit: 3721

assembly having a pulley mechanism 48 operatively associated with a driver (see figs. 3-4) for the purposes of efficiently effecting movement of said driver. The substitution of Fontayne's flexible actuator link 155 by a pulley mechanism such as shown by Bolanos would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of one known and equivalent mechanism (a pulley mechanism as taught by Bolanos) for another (a flexible actuator link as taught by Fontayne) would have yielded predictable results to one of ordinary skill in the art at the time of the invention and the technique for improving a particular class of devices was part of the ordinary capabilities of a person skill in the art.

With respect to claims 33-34, 36, and 40 Fontayne also discloses a plurality of staples that are aligned in a plurality of linear rows as shown in fig. 4 and a sled 276 which is movable with the dynamic clamping member through the cartridge.

With respect to claim 39, Bolanos teaches wherein the pulley 48 uses cables 32.

With respect to claim 41, Bolanos teaches the concept of a pulley operatively connected to a sled 28.

Response to Arguments

6. Applicant's arguments filed 7/7/08 have been fully considered but they are not deemed persuasive. Applicant contends that neither Fontayne, Bolanos, nor Milliman disclose at least one pulley which effects movement of a dynamic clamping member, and that it is infeasible to incorporate the dynamic clamping member of Milliman into the Bolanos' device. This is not found persuasive as claims are given their broadest reasonable interpretation consistent with the

Art Unit: 3721

specification. In this instance, Milliman is relied upon to modify the dynamic clamping member of Fontayne. Also, it should be noted that Bolanos is relied upon to show the use of a pulley system to effect movement of a staple driver. It is acknowledged that Bolanos' device operates differently from the Fontayne's device as modified by Milliman, however, both (Fontayne and Bolanos) show the use of a flexible drive which effects movement of a staple driver. It would be within the abilities of one having ordinary skill in the art to apply Bolanos' concept of using a pulley to the modified invention of Fontayne in order to effect movement of a dynamic clamping member, such as taught by Milliman, assuring a uniform and consistent movement of said clamping member through the tool assembly during ejection of staples.

7. In response to Applicant's argument that the incorporation of Milliman drive assembly 212 including working head 268 into Fontayne's apparatus, would provide no need for Fontayne's clamp member 90 or benefit to providing the clamp member, it has been held that: the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In the instant case, the clamp member 90 of Fontayne is relied upon to show the teaching of maintaining the proximal end of the anvil and cartridge assembly in juxtaposed alignment with each other during the stapling procedure and the dynamic clamping member of Milliman is relied upon to show the teaching of defining a maximum gap adjacent said dynamic clamping member during forward movement of it through the tool assembly.

8. For the reasons above, the grounds of rejection are deemed proper.

Art Unit: 3721

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Lopez whose telephone number is 571-272-4464. The examiner can normally be reached on Monday - Thursday: 8:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3721

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ML/

Patent Examiner

/Rinaldi I Rada/

Supervisory Patent Examiner, Art Unit 3721